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A randomised controlled trial to evaluate the role of the continuous glucose monitoring system (CGMS) in pregnancies complicated by pre-existing diabetes

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
07/10/2008

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0254145814

Study information

Scientific Title

Study objectives
The principal question is whether more detailed assessment of blood glucose levels using the CGMS system will improve glycaemic control throughout pregnancy without an excessive increase in rates of hyperglycaemia and thereby reduce both maternal and perinatal morbidity. In addition this will allow us to assess the relative contribution of different blood glucose parameters I.e. fasting Vs postprandial to measures of glycaemia (HbA1c) and foetal growth throughout gestation and neonatal hyperinsulinsemia. The effects of intensive monitoring on self-efficacy and quality of life will also be measured. We will also examine in more detail then hitherto possible the frequency, severity and management of hypoglycaemia in pregnancy. A detailed economic evaluation of the costs and benefits of the intervention will also be a vital component of this study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Collaborative, open-label, randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Diabetes

Interventions
A collaborative, open-label, randomised controlled trial with participants allocated to either standard antenatal care or CGMS which will be performed monthly in addition to standard care.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Infants:
1. Perinatal outcome assessed will be gestational age
2. Body weight
3. Respiratory distress (1 and 5 minute apgar scores)
4. Admission to special care baby unit with hypoglycaemia or hyperbilirubinaemia
5. Cord blood measurements of adiposity and hyperinsulineamia

Mothers:
1. Glycaemic control
2. Frequency and severity of hypoglycaemia
3. Presence and /or progression of retinopathy
4. Mode of delivery
5. Delivery related complications
6. Diabetes related distress questionnaire
7. Individually generated index of quality of life measure

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Target total across all sites = 120.
Inclusion: All women with pre-existing diabetes attending Ipswich or Norwich antenatal diabetes centre.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
None other than serious medical or psychological co-morbidity which would interfere with the subjects ability to participate.

Date of first enrolment
08/04/2004

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Ipswich Hospital NHS Trust
Ipswich
United Kingdom
IP4 5PD

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital NHS Trust (UK) NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	25/09/2008		Yes	No